

EXHIBIT C

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ILLINOIS**

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IN RE YASMIN AND YAZ : 3:09-md-02100-DRH-PMF
(DROSPIRENONE) MARKETING, :
SALES PRACTICES AND RELEVANT : MDL No. 2100
PRODUCTS LIABILITY LITIGATION :
Judge David R. Herndon

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This Document Applies To All Actions X

DECLARATION OF SHARON BROWN

1. I am employed by Bayer HealthCare Pharmaceuticals Inc. (BHCP) in the position of Director - Global Regulatory Affairs – Women’s Healthcare and Diagnostic Imaging. BHCP filed the applications for and holds the marketing authorization from the FDA to market and sell Yasmin and YAZ in the United States. I am familiar with many of the general types and categories of documents concerning Yasmin and YAZ created, maintained or received by BHCP in the course of its business, and including categories of documents discussed below.
2. I have been informed that plaintiffs in this lawsuit have asked that the Court remove the confidentiality designations in regard to certain documents produced in this litigation that plaintiffs would intend to make public following removal of the confidentiality designation. I offer this declaration in support of the confidentiality designations that were made as to various categories of these documents.

Protection of Confidential Information

3. In their employment contracts BHCP employees agree to maintain the confidentiality of business data which come to their attention during business employment. The confidentiality requirement is reinforced in company policies and practices. Physical access to BHCP’s facilities in New Jersey is restricted by security monitoring and similar means. Company practice requires that visitors be escorted by a company employee while in the facility. Consultants or other third parties who are provided with proprietary information from BHCP similarly are required to sign an agreement to maintain the confidentiality of business data.
4. BHCP’s computer networks utilize firewalls to prevent unauthorized access to its electronic systems. Among other features, access to the networks requires use of login and password identification which employees are required to maintain in confidence, plus simultaneous use, when necessary, of an electronic security token.

5. Access to the company's proprietary data is based on need. For example, BHCP's regulatory files for Bayer products, including Yasmin and YAZ, are maintained in a database that has permission-based security access and restricts viewing and retrieval to authorized employees whose job duties require access to the materials. Similar restrictions are in place in regard to the electronic files of preclinical and clinical study materials for Bayer products including Yasmin and YAZ. Copies of reports of developmental, toxicological, and clinical studies, and related materials, are maintained on secure databases and file systems that also have permission-based security access and restrict viewing and retrieval to authorized employees whose job duties require access to such materials.

Confidentiality of documents challenged by plaintiffs

6. Due to the competitive nature of the oral contraceptive market, pharmaceutical companies invest substantial time and money developing "competitive intelligence". This makes information concerning a competitor's research, product development and testing, manufacturing, marketing, finance and regulatory activities and strategies of substantial commercial value. For example, a single clinical study can require thousands of man hours of work and depending on the size of the study hundreds of thousands, if not millions, of dollars in expenditures to plan, implement, analyze and report. Yasmin and YAZ have been the subject of dozens of clinical studies. Information concerning competitors' studies is of substantial value to other contraceptive manufacturers, because it can inform their own research and development, as well as their marketing efforts, and allow them to avoid some or all of the cost of developing their own plans.

7. Access to details about studies and study data for Yasmin and YAZ would allow other oral contraceptive manufacturers to utilize them in their own drug applications at no cost. Similarly, public disclosure of past, ongoing and future research would allow any competitor to develop counter-strategies to downplay or offset the market effect of those studies. Public disclosure of this proprietary research would unfairly make them an unwilling R&D arm of their competitors.

8. Confidential documents that plaintiffs seek to make publicly available include study reports and data from the development and testing of Yasmin and YAZ, including the documents identified as items 3 through 7, 9, 16, and 25 on the document titled Plaintiffs' Steering Committees' Sealed Addendum To Document 2051 ("PSC Addendum"). These documents have not been publicly disclosed. When such reports and data are provided to the FDA, BHCP is aware of and relies on the fact that such proprietary study information is treated by the FDA as confidential under various laws and regulations.

9. Study reports and data were and are provided by BHCP to the FDA as part of the drug application and regulatory oversight processes. However BHCP protects this information by submitting it as confidential data, and the FDA treats such information as being confidential and proprietary. While summaries of the nature and results of studies are made available to the public, the specific details in study reports and data are protected by the FDA as proprietary commercial data and are not made available to the public.

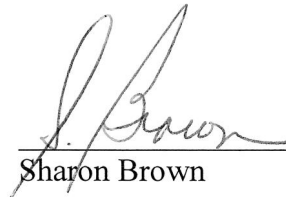
10. Unpublished clinical and preclinical study reports, and related documents in individual employee's files, contain proprietary information that another oral contraceptive manufacturer would find valuable in competing against BHCP in the contraceptive market. Study reports disclose in detail the protocols and methodologies applied in the study. Related documents in individual employees files contain comparative information concerning competing products, plans for studies to be conducted in the future, explanations of the rationales for past, ongoing or future studies including extensions of product use indications, information concerning the development of new products, and similar matters.

11. In some instances, study protocols are developed by a third party hired by BHCP to design and conduct of the study and contain information and descriptions of study techniques that are proprietary to the third party. Those third parties demand and expect that BHCP will take steps to protect the confidential nature of their proprietary information. For example, one of the confidential documents is the study report prepared by Ingenix/i3 Drug Safety (PSC Addendum Item 11) which is labeled as containing confidential and proprietary information of Ingenix provided solely for the use of BHCP. Additionally, PSC Addendum Item 13 is an interim report of the LASS study. BHCP understands the study investigator intends to seek publication of a report on the study findings in peer-review medical journals, and public release of the interim LASS report may interfere with or prohibit journal publication.

12. Other documents plaintiffs seek to make public contain information of BHCP that competitors would find valuable in marketing their own products and competing against Yasmin and YAZ. This includes internal documents, which I understand or believe are confidential, containing observations and guidance from external healthcare providers experts (PSC Addendum Item 30), documents identifying or discussing healthcare providers who are leaders in their respective fields and who are appropriate persons from whom Bayer could to seek consultation regarding women's health products including Yasmin and YAZ (PSC Addendum Items 45, 47, 49, 50, 51, 53, 56), and a report on trends in the development and marketing of oral contraceptives (PSC Addendum Item 46). Information concerning marketing and product development plans, and concerning persons who BHCP considers as leaders in the women's health medical community, who it may desire to use as consultants and, as reflected in some of the documents, that provides details of the consultations provided, would be valuable to competitors in their marketing of competing products.

I declare that the foregoing statements are true and correct to the best of my knowledge, information and belief.

Dated: November 9, 2011


Sharon Brown